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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,025	10/30/2003	Carlos Schuler	0150.00	7124
21968	7590	09/28/2007		
NEKTAR THERAPEUTICS 201 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER DOUGLAS, STEVEN O	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 09/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,025

Applicant(s)

SCHULER ET AL.

Examiner

/Steven O. Douglas/

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 18-20, 26, 28, 31, 40, 42, 48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16, 17, 21-25, 27, 29, 30, 32-39, 41, 43-47 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06292004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species H (Fig. 8) in the reply filed on 8/16/07 is acknowledged. The traversal is on the ground(s) that Applicant does not fully understand the listing as set forth by the Examiner since several of the items listed by the Examiner belong to the same species. This is not found persuasive because a proper traversal (as pointed out in the election of species) should include evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. Thus a mere statement that Applicant does not fully understand the listing as set forth by the Examiner since several of the items listed by the Examiner belong to the same species is not proper. Accordingly, claims 14,15,18-20,26,28,31,40,42,48 and 50 are withdrawn from further consideration by Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

It appears to Examiner that current listing of the claims appear to be a poor quality copy of a clean original set of claims (i.e. either degraded by a poor fax transmission or scanner). Examiner respectfully requests a clean copy or set of claims in response to the current office action if Applicant chooses to respond thereto.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al (US Pat. 5,183,187).

The Martin et al. reference discloses an aerosolization apparatus comprising a container 11 containing a pharmaceutical formulation a metering chamber (proximate reference numeral 31), a valve assembly 13 and a pressurizer 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13,16,17,21-25,27,32-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al.

The Martin et al. reference discloses a medicament dispensing apparatus (supra), but does not disclose the metering chamber as being sized so at least 2 mg of active agent is aerosolized (claim 1 and 32), the metering chamber as being sized so at least 3 mg of active agent is aerosolized (claim 5 and 34), the metering chamber as being sized so at least 5 mg of active agent is aerosolized (claim 6 and 35), the metering chamber as being sized to contain at least 50

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μm (claim 7), the metering chamber as being sized to contain at least 150 μm (claim 8 and 21), the metering chamber as being sized to contain at least 300 μm (claim 9), the pressurizer is arranged so that at least 50% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 10,24 and 36) or the pressurizer is arranged so that at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 11 and 37). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the metering chamber as being sized so at least 2 mg of active agent is aerosolized (claim 1 and 32), the metering chamber as being sized so at least 3 mg of active agent is aerosolized (claim 5 and 34), the metering chamber as being sized so at least 5 mg of active agent is aerosolized (claim 6 and 35), the metering chamber as being sized to contain at least 50 μm (claim 7), the metering chamber as being sized to contain at least 150 μm (claim 8 and 21), the metering chamber as being sized to contain at least 300 μm (claim 9), the pressurizer is arranged so that at least 50% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 10,24 and 36) or the pressurizer is arranged so that at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 11 and 37), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regard to claims 32-39 and 41, the method as claimed would be inherent during the normal use and operation of resulting device.

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Claims 29,30,43-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. as applied to claims 1-13,16,17,21-25,27,32-39 and 41 and further in view of Riebe et al. (US Pat. 6,644,306).

The Martin et al. reference discloses a medicament dispensing apparatus (supra), but does not disclose an aerosolized agent as being insulin. The Riebe et al. reference discloses another medicament dispensing apparatus arranged for dispensing the active ingredient insulin in order to treat a patient for diabetes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Martin et al. device to dispense insulin in view of the teachings of the Riebe et al. reference to treat a patient for diabetes.

In regard to claims 43-47 and 49, the method as claimed would be inherent during the normal use and operation of device resulting from the combination of references.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Meshberg, Gallia and Ward references pertain to aerosol dispensers with associated metering chambers and pressurizers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
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SD
9-24-07